Section 8: 510(k) Summary

MAY 3 1 2013

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92 is below:

Submitter Information:	
Name	Adhezion Biomedical, LLC
Address	One Meridian Boulevard Suite 1B02 Wyomissing, PA 19610
Phone Number	(484) 334-2929
Fax Number	(610) 373-2081
Establishment Registration	3006385287
Name of contact person	Caridad Smith, Sr. Manager of Regulatory Affairs and Quality Assurance
Date prepared	May 28, 2013
Name of Device(s):	
Trade or proprietary name	SURGISEAL ® Stylus™ and Stylus Twist™ Topical Skin Adhesive
Common or usual name	Device, Tissue Adhesive for Topical Approximation
Classification name	Class II
Classification Panel	General and Plastic Surgery Devices
Regulation	Class II, under 21 CFR 878.4010
Product Code(s)	MPN
Legally Marketed device(s) to which equivalence is claimed	SURGISEAL® Topical Skin Adhesive (K082993) DERMABOND NX (DERMABOND Advanced ® - (K100423) Derma+Flex QS (K101276)
Reason for 510(k) submission	Modification to Currently Marketed Device
Device Description	SURGISEAL Stylus and Stylus Twist Topical Skin Adhesive are sterile, professional liquid topical skin adhesives containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. Each applicator is comprised of a plastic ampoule container contained within an applicator sleeve with the applicator tip. This Stylus applicator tray is contained in an outer Tyvek pouch. When SURGISEAL is applied to the skin, it polymerizes in minutes.
Indications for use	SURGISEAL Topical Skin Adhesive is intended for topical applications only to

	hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations. SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures.
Technological Characteristics	The technological characteristics of SURGISEAL Stylus™ and Stylus Twist™ Topical Skin Adhesive are equivalent in performance to the predicate device SURGISEAL Topical Skin Adhesive. SURGISEAL product family consists of a monomeric (2-octyl cyanoacrylate) liquid adhesive formulation packaged in a single-use applicator. The device is a low viscosity formulation to allow for varied layered applications of the adhesive to the intended area and allow for either a single thick, continuous layer or two thin layers of the adhesive to the wound area. SURGISEAL product family is used for topical applications only to hold closed easily approximated skin edges of wounds. The differences between the proposed devices SURGISEAL Stylus™ and Stylus Twist ™ Topical Skin Adhesive; and the predicate devices are the following: The currently marketed, SURGISEAL® Topical Skin Adhesive, single use applicator consists of a thermal formed LDPE/PP/Polyacrylonitrile (Barex 210) foil heated seal on a PET/Aluminum/Polyacrylonitrile backing with attached Polyurethane foam with a PE Layer, which is supplied at a volume of about 0.35 mL The proposed devices SURGISEAL Stylus™ and Stylus Twist ™ Topical Skin Adhesives, single-use applicator consists of a a thermal formed LDPE/PP/Polyacrylonitrile (Barex 210) adhesive Ampoule with an Aluminum ampoule lid including a plastic inner layer (seal). The applicator sleeve is MDPE, which are supplied at a volume of ≥ 0.5mL. o The SURGISEAL Stylus has a Nylon fiber foam tip. o The SURGISEAL Stylus Twist has a HDPE composition foam tip.
Substantial Equivalence	<u>Biocompatibility:</u> The biocompatibility testing of the adhesive, that was previously conducted to the currently marketed device, SURGISEAL (K082993) per the International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing" is deemed supportive of the proposed devices, SURGISEAL Stylus™ and Stylus Twist ™ Topical Skin Adhesive. Based on the lack of changes to the formulation, there was no additional biocompatibility testing of the adhesive conducted to support the requirements for biological evaluation of devices for the prolonged exposure.. The following biocompatibility testing was performed on the Stylus product(s):

Biocompatibility Test	Test Description	Summary of Results	Results
Cytotoxicity - (SURGISEAL™ Stylus Topical Skin Adhesive Flock Tip (Lot James A))	ISO 10993-Part 5 – Test for *In-Vitro* Cytotoxicity	No Cytotoxic Effect	PASS
Cytotoxicity – SURGISEAL™ Stylus Twist™ Topical Skin Adhesive (Lot x 5923)	ISO 10993-Part 5 – Test for *In-Vitro* Cytotoxicity	No Cytotoxic Effect	PASS
ISO Intracutaneous Reactivity Test – SecureSeal™ (Lot 121512i)	ISO 10993-10: Test for Irritation and Skin Sensitization	No Dermal Reactions	PASS
Primary Skin Irritation SecureSeal™ - (Lot 121512i)	ISO 10993-10: Test for Irritation and Skin Sensitization	No Dermal Irritations	Pass

Based on the results from those studies, the proposed devices are considered to be non-cytotoxic, and non-irritants.

Performance Testing:

The following testing was performed on the proposed devices, SURGISEAL Stylus™ and Stylus Twist™ Topical Skin Adhesive is listed below:

- Flexibility
- *In-vitro* wound closure
- Viscosity
- Set-time
- Purity
- Surface Coverage
- Linear Coverage

The performance testing identified above demonstrated that the applicator design modification to the currently marketed product does not impact the performance specification criteria identified for the SURGISEAL product family.

Sterilization and Shelf-Life

The proposed devices, SURGISEAL Stylus™ and Stylus Twist ™ Topical Skin Adhesive are sterilized in accordance with the order of operation of the assembly. First to be sterilized is the filled ampoule containing the adhesive, by gamma irradiation in accordance with ISO 11137-2:2006. Then the finished bulk applicator in the secondary packaging is sterilized by ethylene oxide in accordance

	with ISO 11135-1:2008 and ISO 11135-2:2008. The SURGISEAL Stylus™ and Stylus Twist ™ Topical Skin Adhesive does not impact the 24 month (2 year) expiration date (shelf-life) proposed for these products. Real-time and accelerated aging studies were performed using the STYLUS products and they demonstrated the same performance characteristics as the currently marketed, predicate device SURGISEAL Topical Skin Adhesive (K082993). The proposed devices, SURGISEAL Stylus™ and Stylus Twist ™ Topical Skin Adhesive will be labeled with a two (2) year expiration date.

Based on extensive bench performance testing, the proposed devices SURGISEAL Stylus™ and Stylus Twist ™ Topical Skin Adhesive, in comparison to predicate device, SURGISEAL (K082993) have demonstrated to be safe and efficacious per the performance studies.

The order of operation of a two-part sterilization process of the proposed devices, SURGISEAL Stylus™ and Stylus Twist ™ Topical Skin Adhesive, is necessary in order to sterilize the product and achieve a 10^{-6} SAL, while supporting the labeling of the medical device as "sterile". In order to maintain the expected performance of the devices, in accordance with the currently marketed SURGISEAL device properties/specifications of the device SURGISEAL remains unaffected and therefore provides further assurance of substantial equivalence, as documented throughout the submission

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Adhezion Biomedical, LLC
% Ms. Caridad Smith
Sr. Manager of Regulatory Affairs/
Quality Assurance
One Meridian Parkway, Suite 1B02
Wyomissing, Pennsylvania 19610

May 31, 2013

Re: K130474
Trade/Device Name: SURGISEAL Stylus™ Topical Skin Adhesive and SURGISEAL Stylus™ Twist Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: May 07, 2013
Received: May 08, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR
Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5: Indications for Use

510(k) Number (if known): TBD K130474

Device Name(s): SURGISEAL Stylus™ Topical Skin Adhesive
SURGISEAL Stylus Twist™ Topical Skin Adhesive

Indications for Use:

SURGISEAL Topical Skin Adhesive is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations.

SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures.

Prescription Use X **AND/OR** **Over-The-Counter Use**_____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130474